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Medication errors: definitions and classification

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1. To understand medication errors and to identify preventive strategies, we need to classify them and define the terms that describe them.
2. The four main approaches to defining technical terms consider etymology, usage, previous definitions, and the Ramsey–Lewis method (based on an understanding of theory and practice).
3. A medication error is 'a failure in the treatment process that leads to, or has the potential to lead to, harm to the patient'.
4. Prescribing faults, a subset of medication errors, should be distinguished from prescription errors. A prescribing fault is 'a failure in the prescribing [decision-making] process that leads to, or has the potential to lead to, harm to the patient'. The converse of this, 'balanced prescribing' is 'the use of a medicine that is appropriate to the patient's condition and, within the limits created by the uncertainty that attends therapeutic decisions, in a dosage regimen that optimizes the balance of benefit to harm'. This excludes all forms of prescribing faults, such as irrational, inappropriate, and ineffective prescribing, underprescribing and overprescribing.
5. A prescription error is 'a failure in the prescription writing process that results in a wrong instruction about one or more of the normal features of a prescription'. The 'normal features' include the identity of the recipient, the identity of the drug, the formulation, dose, route, timing, frequency, and duration of administration.
6. Medication errors can be classified, invoking psychological theory, as knowledge-based mistakes, rule-based mistakes, action-based slips, and memory-based lapses. This classification informs preventive strategies.

To understand medication errors and identify preventive strategies, and to set in context the papers on medication errors in this special issue of the *British Journal of Clinical Pharmacology*, it is necessary to define the term 'medication error' and associated terms and to classify the different types of error.

The art of definition

To define something (Latin *definire*) is to determine its boundaries (Latin *fines*), and hence to state exactly what the thing is or to set forth or explain its essential nature; this is what Aristotle called τό τί ἦν εἶναι (literally, that which is). Thus, a definition is 'a precise statement of the essential nature of a thing; a statement or form of words by which anything is defined' [1].

There are different types of definition. The simplest is the descriptive definition, such as is found in an ordinary dictionary. A cat, for example, is 'a carnivorous quadruped which has long been domesticated, being kept to destroy mice, and as a house pet' [1]. Such definitions may suffice in some cases, when all that is needed is to describe what a thing is, but are often inadequate for technical terms. For these we usually need something more – a stipulative definition, one in which one stipulates 'what [a term] shall be used to mean' [1]. Such definitions should also be what is called 'intensional'; in other words, they should specify the necessary and sufficient conditions that make a thing a member of a specific set. The definitions given here are all of this kind. In contrast, other types of definition are generally not of value; they include extensional definitions, which consist of lists naming every object that is a member of a specific set, and ostensive definitions, which give the meaning by pointing or illustrating.

There are five desiderata for a definition:

- it must describe all the essential attributes of the thing being defined, i.e. it must encapsulate its true essence;
- it should avoid circularity – one should not, for example, define a horse simply as 'a member of the species Equus', nor do as Dr Johnson did in his 1755 dictionary and unhelpfully define a hind as 'the she to a stag' and a stag as 'the male of the hind';

• it must not be too wide or too narrow – it should not omit anything of importance, but neither should it include any things to which the defined term does not apply;
• it must not be obscure – one should use commonly understood terms with clear meanings and not terms that themselves need further definition, although with technical terms this may be difficult and even sometimes impossible;
• it should be positive if possible, not negative; one should not, for example, define wisdom as the absence of folly – one should say what it is, not what it is not.

The difficulty in defining a word or a term is generally underestimated by those who are not professional lexicographers. Many think that it is something that can be done by a few experts sitting around a table for a few minutes at the beginning of a meeting, before the serious work begins. However, the history of lexicography shows that lexicographers have struggled to produce clear, unambiguous and accurate definitions for even the simplest definienda, despite great difficulties [2], and sometimes with highly controversial results [3].

There are four methods of approaching the problem of definition of technical terms: through etymology, through usage, by examining previous definitions, and by the Ramsey–Lewis method, a method in which a group of terms appearing in a theory can be defined implicitly by the assertions of the theory itself [4]; this can be extended to adduce a knowledge of the practices that are relevant to the term being defined. A fifth method, that of dichotomy, is not usually useful in framing definitions of technical terms, although it may occasionally be useful in checking the soundness of a definition [5].

Etymology

Before the modern lexicographic era, which started in the second half of the 19th century, definition was regarded as stemming solely from etymology. This approach is still sometimes sufficient to generate useful definitions. Take polymyalgia: it comes from three Greek words meaning pain in many muscles, which is how it is defined in the *Oxford English Dictionary* [1]. However, even with relatively simple terms like this, it is vital to understand the exact meanings of the words in the original language from which the English words or morphemes are derived. For example, polydactyly means not just many fingers, but *too* many fingers. The prefix poly- comes from the Greek word πολύς (polus), which had many different meanings: long (of time), large, wide, or far (of space), much or great (of value or worth), much or mighty (of size), and many or too many (of number). It is this last ambiguous meaning that is used in English words that start with poly-. In each case poly- means either many or too many. However, in one word it can mean both: polypharmacy – the use of many drugs (appropriately) or the use of too many drugs (inappropriately). Which meaning you choose may affect your view of polypharmacy [6].

Usage

By the time James Murray and his colleagues were ready to begin work on the *New English Dictionary* (later to be called the *Oxford English Dictionary*) in around 1870, it was recognized that in addition to etymology it was important to take into account the history of the usage of the definiendum [7], a principle that was enshrined in the lexicographic rules that they devised, reflected by Richard Chenevix Trench's epigrammatic observation that 'every word should be made to tell its own story' [8]. In doing so, they were observing Aristotle's dictum that 'a definition should refer to what is prior and better known' [9]. This approach recognizes the philosophical views that 'no word has a meaning inseparably attached to it; a word means what the speaker intends by it, and what the hearer understands by it, and that is all' [10], and that 'for a large class of cases – though not for all – in which we employ the word "meaning" it can be defined thus: the meaning of a word is its use in the language' [11].

The importance of taking usage into account can be seen from two simple examples. 'Ban', originally meant to speak but now means to prevent from speaking [12], a change in usage that has gradually occurred over about 400 years. 'Rheumatic', which comes from the Greek word ῥέειν (rheein), to flow, originally meant pertaining to rheum, a watery secretion or discharge. In the 16th century it came to mean 'having a rheumy defluxion' or 'full of watery mucus'. Then because of contemporary theories about fluxes in the causation of disease, its meaning became 'relating to rheumatism' and in the 18th century 'subject to rheumatic pain'; it was later applied to rheumatic fever. Modern usage relates to the later meanings, but they also depend on context.

It is also well to remember that a word can mean different things to different people or even in different circumstances. In some mathematical applications, for example, 'parameter' means 'a quantity which is fixed (as distinct from the ordinary variables) in a particular case considered, but which may vary in different cases', whereas in other cases it means 'an independent variable' [1].

Previous definitions

Attempts are often made by committees to define a technical term. Many such definitions are unsatisfactory and have been handed down as *ex cathedra* statements, without any indication of the thought processes that have gone into producing them. In addition, as others have pointed out, disagreement within such committees is rife, and consensus in health care is often based on compromise, reached only on 'bland generalities that represent the lowest common denominator of debate and are embalmed as truths' [13].

Nevertheless, such definitions may be useful in formulating new and better ones, since they may contain helpful ideas. The principle is to examine published definitions critically, in light of the five desiderata enumerated above,

and to produce a definition that incorporates what is relevant and omits what is not, adding relevant features that may have previously been missed. In order to identify the last of these, the next method may be useful.

The Ramsey–Lewis method

In the Ramsey–Lewis method [4] the meaning of a term is given implicitly by the relevant scientific theory, including all the assertions that it makes about the term. How, for example, would you define 'oxygen'? The answer is to consider the true statements that have been made about it, or rather those that are considered to be true at the time. At a certain time oxygen might have been defined as 'dephlogisticated air'. Now it is defined as 'a non-metallic chemical element, atomic number 8, which as a colourless, odourless gas with diatomic molecules (O_2), forms approximately one-fifth of the earth's atmosphere, is essential for aerobic respiration, and is the chief agent of combustion, rusting of metals, etc., and which is also a constituent of numerous compounds, including water, many organic substances, and many minerals' [1]. Our theories and knowledge about oxygen allow us to define it. This example yields a descriptive definition, but stipulative intensional definitions are also possible within this framework. In the case of clinical terms one can add to this system an understanding of the practical aspects of the relevant theory.

Defining terms in medication errors

All of these methods have been adduced by Aronson and Ferner in their approach to defining terms relevant to drug safety terminology [14] and medication errors [15] and by Hauben and Aronson in defining the term 'signal' in pharmacovigilance [16]. I shall not reiterate all the arguments here.

A medication

Like many terms of this form (e.g. 'definition', 'prescription'), 'medication' can mean either a process or an object that undergoes the process. A medication (the object) can be considered to be the same as a medicinal product, which has been defined in terms of what a medicinal product is and what it does. Thus, a medication is '[a product that] contains a compound with proven biological effects, plus excipients, or excipients only; it may also contain contaminants; the active compound is usually a drug or prodrug, but may be a cellular element' [14].

There is a codicil to this definition, which is not strictly part of the definition, but describes certain attributes of a medicinal product. The codicil stipulates that a medicinal product is one that is intended to be taken by or administered to a person or animal for one or more of the following reasons: as a placebo; to prevent a disease; to make a diagnosis; to test for the possibility of an adverse effect; to modify a physiological, biochemical, or anatomical function or abnormality; to replace a missing factor; to ameliorate a symptom; to treat a disease; to induce anaesthesia. Medication (the process) is the act of giving a medication (the object) to a patient for any of these purposes.

This definition reminds us of the distinction between the drug itself (the active component) and the whole product. It includes chemical compounds, either drugs or prodrugs (which themselves may have no pharmacological activity), or, in racemic mixtures, stereoisomers that may have only adverse effects, or compounds that are used for diagnostic purposes (such as contrast media); it also includes cellular elements, such as inactivated or attenuated viruses for immunization, blood products (such as erythrocytes), viruses for gene therapy, and embryonic stem cells; 'contaminants' includes chemical and biological contaminants and adulterants, the former being accidentally present, the latter deliberately added.

Thus, the definition covers a wide range of compounds. However, it does not include medications when they are used to probe systems for nondiagnostic purposes, such as the use of phenylephrine to study baroreceptor reflexes in a physiological or pharmacological experiment.

An error

An error is 'something incorrectly done through ignorance or inadvertence; a mistake, e.g. in calculation, judgement, speech, writing, action, etc.' [1] or 'a failure to complete a planned action as intended, or the use of an incorrect plan of action to achieve a given aim' [17]. Other definitions have been published [18].

A medication error

With these definitions in mind, a medication error can be defined as 'a failure in the treatment process that leads to, or has the potential to lead to, harm to the patient' [15]. The use of the term 'failure' signifies that the process has fallen below some attainable standard. The 'treatment process' includes treatment for symptoms or their causes or investigation or prevention of disease or physiological changes. It includes not only therapeutic drugs but also the compounds referred to above. It also includes the manufacturing or compounding, prescribing, transcribing (when relevant), dispensing, and administration of a drug, and the subsequent monitoring of its effects. 'Harm' in the definition also implies 'lack of benefit', a form of treatment failure. Note that the definition does not specify who makes the error – it could be a doctor, a nurse, a pharmacist, a carer, or another; nor does it specify who is responsible for preventing errors.

Different definitions of medication errors have been tested, as all technical definitions should be. In this case it was done by devising scenarios and determining which would constitute an error under each of the definitions.

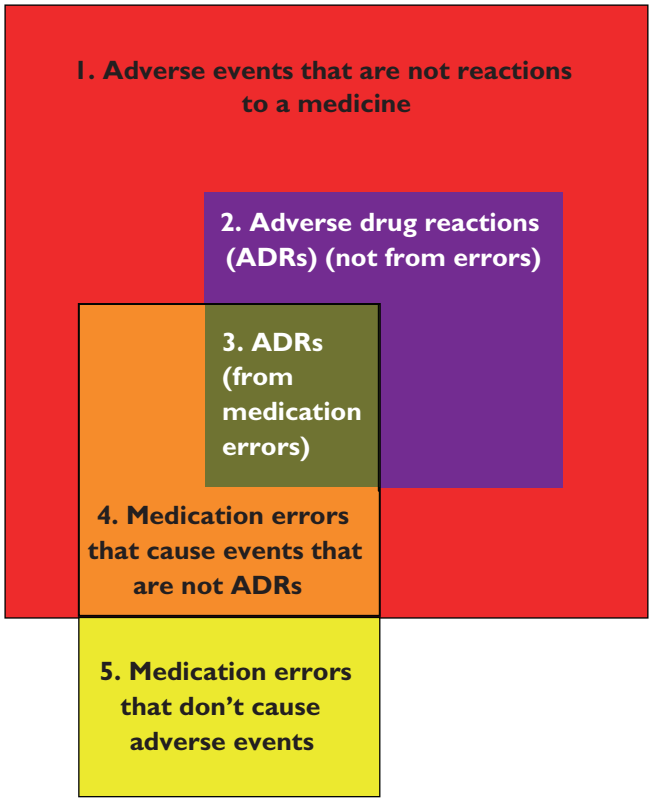

Figure 1

A Venn diagram showing the relation between adverse events, adverse drug reactions, and medication errors; the sizes of the boxes do not reflect the relative frequencies of the events illustrated (reproduced from references 14 and 15, with permission from Wolters Kluwer Health/Adis©; Adis Data Information BV (2005, 2006); all rights reserved)

The above definition, slightly amended, was the only definition that categorized all error scenarios, and only error scenarios [18].

Figure 1 shows how medication errors, defined in this way, fit into the overall pattern of adverse drug reactions [14, 15].

Prescribing faults, prescription errors, and balanced prescribing

The two terms 'prescribing' and 'prescription' must be distinguished. 'Prescribing' is (i) the process of deciding what to prescribe and naming it (e.g. 'I prescribe rest and relaxation'); and (ii) the act of writing the prescription. 'Prescription' is (i) the act of writing a prescription; and (ii) the prescription itself. Because of this ambiguity, it is best to use 'prescribing' to mean the decision-making process and 'prescription' the act of writing the prescription.

Various types of faults can occur in the decision-making process: irrational prescribing, inappropriate prescribing, underprescribing, overprescribing, and ineffective prescribing. These form a class of errors, but are different in type from the class of errors that can be made in the act of writing a prescription. This leads to the distinct concepts of 'prescribing faults' and 'prescription errors', a distinction that has not previously been made. The term 'prescribing errors' ambiguously encompasses both of these.

Adapting the definition of a medication error, a prescribing fault can be defined as 'a failure in the prescribing process that leads to, or has the potential to lead to, harm to the patient'. A previous definition, which resulted from a Delphi process (a form of committee) [19], stated that 'a clinically meaningful prescribing error occurs when, as a result of a prescribing decision or prescription writing process, there is an unintentional significant (i) reduction in the probability of treatment being timely and effective; or (ii) increase in the risk of harm when compared with generally accepted practice'. However, this rules out prescribing faults that do not result in harm, and ignores the fact that it is desirable to detect and examine all errors, whether 'clinically meaningful' or significant, since an error indicates a weakness in the system, which might on a future occasion lead to an error of clinical relevance.

A prescription is 'a written order, which includes detailed instructions of what medicine should be given to whom, in what formulation and dose, by what route, when, how frequently, and for how long' [20]. Thus, a prescription error can be defined as 'a failure in the prescription writing process that results in a wrong instruction about one or more of the normal features of a prescription'. The 'normal features' include the identity of the recipient, the identity of the drug, the formulation and dose, and the route, timing, frequency and duration of administration (although this list is by no means exhaustive).

It is possible to define individually the various types of prescribing faults, listed above, but there is considerable overlap amongst them and it is preferable to unify them into a single definition of their opposite, which I call 'balanced prescribing', defined as 'the use of a medicine that is appropriate to the patient's condition and, within the limits created by the uncertainty that attends therapeutic decisions, in a dosage regimen that optimizes the balance of benefit to harm' [20]. This definition excludes all forms of prescribing faults.

Classification of medication errors

The best way to understand how medication errors happen and how to prevent them is to consider their classification, which can be contextual, modal, or psychological. Contextual classification deals with the specific time, place, medicines, and people involved. Modal classification examines the ways in which errors occur (e.g. by omission, repetition, or substitution). However, classification based on psychological theory [21] is to be preferred, as it explains events rather than merely describing them. Its disadvantage is that it concentrates on human rather than

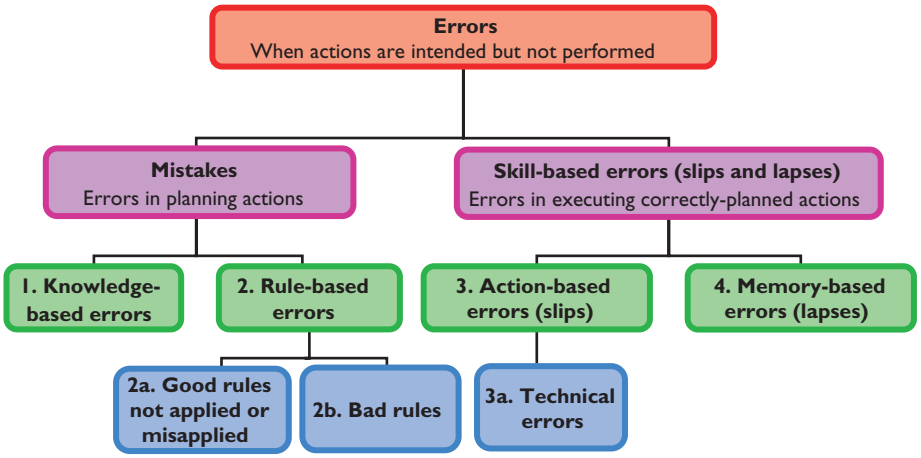

Figure 2

The classification of medication errors based on a psychological approach (reproduced from reference 15, with permission from Wolters Kluwer Health/Adis©; Adis Data Information BV (2006); all rights reserved)

systems sources of errors. These classifications have been discussed in detail elsewhere [15].

Psychologists consider an error to be a disorder of an intentional act, and they distinguish between errors in planning an act and errors in its execution. If a prior intention to reach a specified goal leads to action, and the action leads to the goal, all is well. If the plan of action contains some flaw, that is a 'mistake'. If a plan is a good one but is badly executed, that is a failure of skill.

This approach yields four broad types of medication error (numbered 1–4 in Figure 2) [15, 22]. Mistakes can be divided into (i) knowledge-based errors and (ii) rule-based errors. Failures of skill can be divided into (iii) action-based errors ('slips', including technical errors) and (iv) memory-based errors ('lapses').

Knowledge-based errors can be related to any type of knowledge, general, specific, or expert. It is general knowledge that penicillins can cause allergic reactions; knowing that your patient is allergic to penicillin is specific knowledge; knowing that co-fluampicil contains penicillins is expert knowledge. Ignorance of any of these facts could lead to a knowledge-based error.

Rule-based errors can further be categorized as (a) the misapplication of a good rule or the failure to apply a good rule; and (b) the application of a bad rule.

An action-based error is defined as 'the performance of an action that was not what was intended' [23]. A slip of the pen, when a doctor intends to write diltiazem but writes diazepam, is an example. Technical errors form a subset of action-based errors. They have been defined as occurring when 'an outcome fails to occur or the wrong outcome is produced because the execution of an action was imperfect' [24]. An example is the addition to an infusion bottle of the wrong amount of drug [25].

Memory-based errors occur when something is forgotten; for example, giving penicillin, knowing the patient to be allergic, but forgetting.

Preventing errors through classification

This classification can help understand how errors can be prevented, as discussed in detail elsewhere [15].

Knowledge-based errors can obviously be prevented by improving knowledge, e.g. by ensuring that students are taught the basic principles of therapeutics [26, 27] and tested on their practical application [28] and that prescribers are kept up to date. Computerized decision-support systems can also train prescribers to make fewer errors [29, 30].

Mistakes that result from applying bad rules, or misapplying or failing to apply good rules (rule-based errors), can be prevented by improving rules.

Training can help in preventing technical (action-based) errors.

Memory-based errors are the most difficult to prevent. They are best tackled by putting in place systems that detect such errors and allow remedial actions. Check lists and computerized systems can help.

Conclusion

Medication errors, which can lead to adverse drug reactions, require clear and unambiguous definitions, so that patients, prescribers, manufacturers, and regulators can all understand each other. The classification of medication errors on the basis of the underlying psychological mechanisms, based on how errors occur, can suggest strategies that help to reduce their occurrence.

Competing interests

None to declare.

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